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Treatment patterns and adverse events of antiseizure medications among adult patients with epilepsy: a single centre observational cross-sectional study in Northern Sri Lanka

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Abstract

Background Antiseizure medications (ASMs) are essential for seizure control, but they are also associated with a range of adverse events that may affect treatment outcomes.

Objective This study aimed to evaluate the treatment pattern and adverse events of ASMs among adult patients with epilepsy who were followed up at a tertiary-care hospital in Northern Sri Lanka.

Methods A descriptive cross-sectional study was conducted among adult patients on ASMs for ≥ 3 months who were receiving follow-up at Teaching Hospital Jaffna. Data were collected over four months using a pretested interviewer-administered questionnaire. Chi-square test and logistic regression were performed to determine the significance between groups and the association of independent variables, respectively. A *p*-value of ≤ 0.05 was considered statistically significant.

Results Data from 213 participants was analysed. The mean age was 36.27 ± 0.92 years, and the male-to-female ratio was almost 1. Nearly two-thirds of participants (64.8%) were on dual or polytherapy. Older ASMs were predominantly prescribed (74.5%). A total of 333 adverse events were reported, giving a point prevalence of 68.5% and a rate of 1.6 adverse events per person. Sedation (27%), memory impairment (24%), and dizziness (21%) were the most common adverse events. Advancing age (adjusted OR (AOR): 4.3, 95% CI 1.87 to 10.29, $p < 0.001$), early onset of epilepsy (AOR: 0.35, 95% CI 0.14 to 0.87, $p = 0.023$), and the use of multiple ASMs (AOR: 2.7, 95% CI 1.4 to 5.3, $p = 0.003$) were associated with the occurrence of adverse events. Carbamazepine, clobazam and valproic acid were significantly ($p < 0.05$) associated with one or more common adverse events.

Conclusion Most patients in this study received older antiseizure medications and polytherapy. A high burden of adverse events linked to antiseizure medications was also observed. Studies with larger samples are needed to determine the safety and efficacy of current practices and to plan treatment strategies to optimise the epilepsy care.

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Keywords Epilepsy, Antiseizure medications, Adverse events, Sri Lanka

Background

Epilepsy is a chronic neurological condition that affects almost 52 million people worldwide, and more than 80% of these individuals live in low- and middle-income countries (LMICs) [1]. The global prevalence of epilepsy shows an increasing trend, with a higher burden in socioeconomically disadvantaged countries [1, 2]. Epilepsy significantly affects the quality of life of patients and their families [3, 4]. The primary aim in managing epilepsy is to control seizures effectively, keeping their frequency and severity to a minimum while also reducing the unwanted adverse events of treatment [5].

Antiseizure medications (ASMs) are essential for controlling seizures. Currently more than 20 ASMs, both older and newer ASMs, are used in the treatment of epilepsy [6, 7]. Consumption of ASMs showed considerable variations across the regions, and access gaps were observed in LIMCs [8]. Adverse events are a major concern with ASMs and significantly affect the adherence to ASMs and thereby influence the seizure control [9–11]. Evidence showed that many newer ASMs had fewer adverse events and were better tolerated than older ASMs [8, 12, 13]. However, available data do not indicate superior efficacy of newer ASMs compared to older ASMs [14, 15]. Though newer ASMs are increasingly used nowadays, older ASMs continue to play an important part in the treatment of epilepsy because of their efficacy and affordability, particularly in the LMICs [8, 15–17]. Limited access to better-tolerated ASMs may result in poor adherence, leading to inadequate control and poor quality of life. Moreover, poor seizure control may increase both direct medical costs (hospitalisation for the treatment of an emergency or seizure-related injury) and indirect costs (such as lost wages or productivity and caregiver burden) that may exceed the cost of ASMs.

Sri Lanka, a lower-middle-income country, is affected by a substantial burden of epilepsy. The prevalence among children aged 0–16 years was reported as 57.7 per 10,000 population [18]. Despite this, there is still limited information on how ASMs are used in routine practice and the types of adverse events experienced by patients in the local setting. Therefore, a preliminary study was carried out to examine treatment patterns and ASM-related adverse events among adults with epilepsy attending a public sector tertiary hospital in the Northern Province of Sri Lanka.

Methods

Study design, setting and study population

A descriptive cross-sectional study was conducted among adult patients with epilepsy attending the neurology clinic of the Teaching Hospital, Jaffna. The Teaching Hospital, Jaffna, is the largest tertiary care hospital in the Northern Province of Sri Lanka and provides primary, secondary, and tertiary health care services. As per the clinic records, three hundred and thirty adult patients with epilepsy are being followed up at the neurology clinic of the Teaching Hospital Jaffna.

Adult patients (aged 18 years and older) with epilepsy who had been receiving ASMs for at least three months at the neurology clinic of the Teaching Hospital, Jaffna, were included in this study. Patients who had difficulty in communication were excluded.

Data collection

An interviewer-administered questionnaire was developed through a literature survey and contextualised for the local setting. The content validity of the questionnaire was assessed by two neurologists. As patients attend clinic visits every other month, data collection was conducted over a four-month period from April to August 2024 to recruit the maximum possible number of participants. Eligible participants were approached consecutively during their clinic visits and provided with information about the study. Written informed consent was obtained from all participants prior to enrolment.

Following consent, participants were interviewed using a pre-tested interviewer-administered questionnaire in a private setting to ensure confidentiality and minimise interruptions. Data were collected by two pharmacy graduates who received prior training from the investigators on the study protocol, interviewing techniques, and ethical considerations, including the protection of participant privacy. Personal identifiers were not recorded in the questionnaire, and all collected data were handled confidentially and used solely for research purposes.

Data analysis

Descriptive statistics, such as frequency, percentage, mean, and standard deviation (SD), were used to present the data. Point prevalence and rate of adverse events were determined.

Point prevalence of adverse events was calculated as follows:

$$Point prevelnce = \frac{Number of participants experience adverse effects}{Total number of participants} x100$$

Table 1 Characteristics of the participants

Variable	Frequency (n)	Percentage (%)
Age		
< 40 years	76	35.7
≥ 40 years	137	64.3
Gender		
Male	110	51.6
Female	103	48.4
Educational level		
Primary	43	20.2
Secondary or higher	170	79.8
Type of epilepsy		
Generalised tonic–clonic	74	34.7
Focal	129	60.6
Others	10	4.7
Age of onset of epilepsy		
≤ 12 years	69	32.4
> 12 years	144	67.6
Duration of epilepsy		
< 10 years	69	32.4
≥ 10 years	144	67.6
Number of antiseizure medications		
One medication	75	35.2
Two or more medications	138	64.8
Seizure control		
Free of seizures for less than 2 years	73	34.3
Free of seizures for ≥ 2 years	140	65.7

The rate of adverse events was expressed per person, which was calculated as follows:

$$Rate of adverse events = \frac{Number of adverse effects}{Total number of participants}$$

Adverse events were classified as common (1 in 10 to 1 in 100 individuals) and uncommon (1 in 100 to 1 in 1,000 individuals) adverse events based on their frequency of occurrence according to the World Health Organization–Council for International Organisations of Medical Sciences classification [19].

The chi-square test was used to determine the significance between groups. Logistic regression models were used to determine the factors and ASMs that were associated with adverse events. The association between the occurrence of adverse events and age, gender, education, age of onset, duration of epilepsy, type of therapy, and seizure control was taken, with age < 40 years, males, those who had only primary education, early onset of epilepsy (≤ 12 years), duration of epilepsy < 10 years, monotherapy, and those who had been seizure-free for < 2 years taken as reference groups. The association between individual ASMs and the top three adverse events was determined, adjusting for age, gender, education, age of onset, duration of epilepsy, and seizure control. Results were presented as adjusted odds ratios (AORs) with corresponding 95% confidence intervals (CI). A p-value of ≤ 0.05 was considered statistically significant.

Table 2 Antiseizure medication regimens prescribed to the participants

Medication	Monotherapy n	Dual therapy n	Polytherapy n	Total n (%)
Carbamazepine	35	43	42	120 (56.3)
Valproic acid	20	22	39	81 (38.0)
Clobazam	1	31	34	66 (31.0)
Levetiracetam	14	25	24	63 (29.5)
Clonazepam	-	13	12	25 (11.7)
Topiramate	-	3	20	23 (10.8)
Lamotrigine	3	5	11	19 (8.9)
Phenytoin	2	11	1	14 (6.6)

Approvals

Ethical approval was obtained from the Ethics Review Committee, Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/24/155/NDR/0312), and administrative approvals were obtained from the relevant authorities before the commencement of data collection.

Results

A total of 228 patients with epilepsy visited the neurology clinic during the data collection period. Among them, 216 responded (the response rate was 94.7%). Of the 216 participants, three were excluded from the analysis due to incomplete data.

Characteristics of the participants

Table 1 shows the characteristics of the participants. The mean age of the participants (n = 213) was 36.27 ± 0.92 years, ranging from 19 to 77 years. Gender distribution was nearly equal (males 52% and females 48%). Most of the participants had secondary (n = 111, 52.1%) or higher (n = 59, 27.7%) education. Focal seizure (n = 129, 60.6%) was the most common type of epilepsy. The majority of the participants developed epilepsy after 12 years of age (n = 144, 67.6%) and had it for 10 years or more (n = 144, 67.6%). Almost equal proportions were treated with monotherapy (n = 75, 35.2%) and dual therapy (n = 77, 36.2%), while 28.6% (n = 61) were treated with more than two ASMs. One-third of the participants (n = 73, 34.3%) were seizure-free for two years or more.

Antiseizure medications and treatment pattern

A total of 411 ASMs were prescribed to 213. The number of ASMs prescribed per patient was 1.9. Table 2 summarises the ASMs prescribed to the participants. Among the 411 ASMs prescribed, most (n = 306, 74.5%) were older ASMs. Only one-fourth (n = 105, 25.5%)

were newer ASMs. The five most commonly prescribed ASMs in descending order were carbamazepine (56.3%), valproic acid (38.0%), clobazam (31.0%), levetiracetam (29.5%), and clonazepam (11.7%). Among the top five medications, four belonged to older ASMs. In those on monotherapy, older ASMs were predominantly prescribed (77%). A similar trend was observed in those who were on dual therapy (78%) as well as polytherapy (71%).

When considering the treatment pattern, a greater proportion of patients with generalised tonic–clonic seizures (45.3%) were on monotherapy, compared to those with focal seizures (31.8%). Only one out of ten participants with other seizure types (including absence and myoclonic seizures) was on monotherapy. The commonly prescribed ASMs in patents with generalised tonic–clonic seizures were carbamazepine (41.9%), valproic acid (35.1%), levetiracetam (32.4%), and clobazam (29.7%). Carbamazepine (62.8%), valproic acid (38.7%), levetiracetam (28.7%), and clobazam (28.7%) were the commonly prescribed ASMs in patients with focal seizures too.

Reported adverse events

A total of 333 adverse events were reported in 146 participants with a point prevalence of 68.5%. The rate of adverse events was 1.6 per person. Common adverse events (1 in 10 to 1 in 100 individuals) were sedation (27%), memory impairment (24%), and dizziness (21%). Uncommon adverse events (1 in 100 to 1 in 1,000 individuals) included mood disturbances, fatigue, weight gain, visual disturbances, and hirsutism (Fig. 1).

When considering the seizure types, the overall prevalence of adverse events was almost equal among patients with generalised tonic–clonic seizures (67.6%) and focal seizures (67.4%). Though the prevalence of common adverse events, sedation (33.8% vs. 45.7%), memory impairment (33.8% vs. 36.4%), and dizziness (28.4% vs. 33.3%), was higher among patients with focal seizures compared to those with generalised tonic–clonic seizures, these differences were not statistically significant.

Among the 146 participants who reported adverse events, the dosage was reduced in ten participants. Medication was replaced with an alternative antiseizure medication in 38 participants. The remaining 98 participants were reassured and continued on the same medication. Carbamazepine was the most replaced medication (65.8%). Levetiracetam was the alternative medication in almost all the cases (95%). Table 3 summarises changes in antiseizure medications following adverse events.

Factors associated with adverse events

Figure 2 illustrates the factors associated with the occurrence of adverse events. Occurrence of adverse events was significantly increased with advancing age (AOR: 4.3, 95% CI 1.87 to 10.29, $p < 0.001$), early onset of epilepsy (AOR: 0.35, 95% CI 0.14 to 0.87, $p = 0.023$) and taking more than one ASM (AOR: 2.7, 95% CI 1.40 to 5.30,

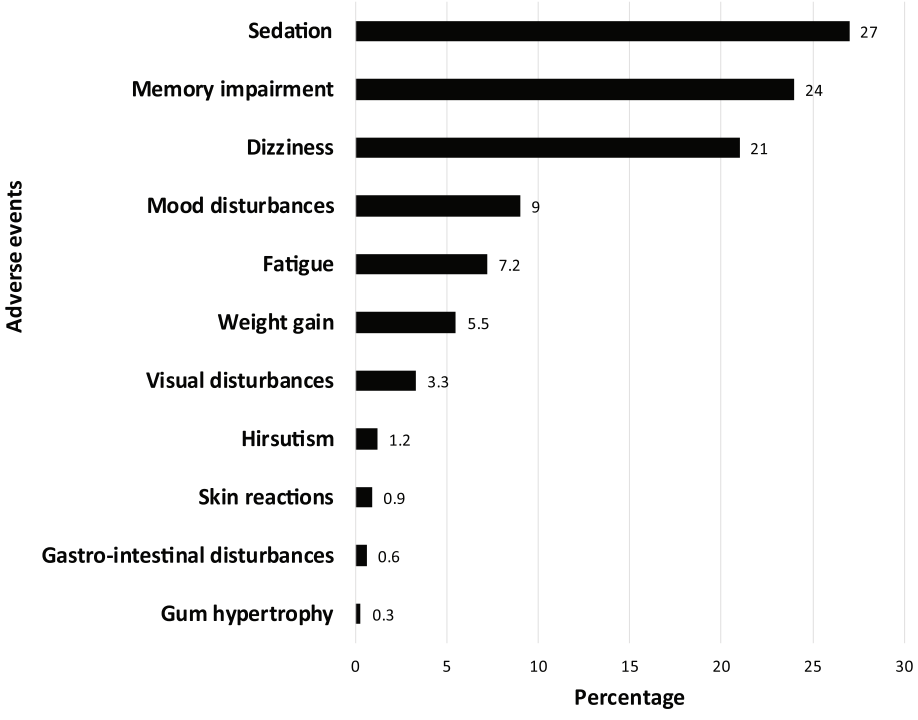

Fig. 1 Prevalence of adverse events among the participants

Table 3 Changes in antiseizure medications following adverse events

Medication	Adverse event	Number of patients	Alternative antiseizure medication
Carbamazepine	Memory impairment	10	Levetiracetam
	Dizziness	6	Levetiracetam
	Drowsiness	4	Levetiracetam
	Skin reactions	3	Levetiracetam
	Elevated liver enzymes	2	Levetiracetam
Valproic acid	Hirsutism	2	Carbamazepine
Phenytoin	Gum hypertrophy	2	Levetiracetam
	Dizziness	5	Levetiracetam
Clobazam	Drowsiness	4	Levetiracetam

$p = 0.003$). Males and females had almost an equal chance of developing adverse events (AOR: 1.1, 95% CI 1.58 to 2.03). Occurrence of adverse events was higher in those who had only primary education (AOR: 0.58, 95% CI 0.23 to 1.49), epilepsy for ≥ 10 years (AOR: 0.75, 95% CI 0.32 to 0.77) and seizure episodes within the past two years (AOR: 1.33, 95% CI 0.68 to 2.61) than their counterparts. However, these observations were not significant.

Table 4 shows the association of antiseizure medications with the common adverse events, adjusted for confounding variables. Valproic acid (AOR: 3.2, 95% CI 1.58 to 6.61, $p < 0.001$) and clobazam (AOR: 2.8, 95% CI 1.44 to 5.54, $p = 0.003$) were associated with sedation. Valproic acid (AOR: 2.5, 95% CI 1.21 to 5.09, $p = 0.013$) and clobazam (AOR: 2.6, 95% CI 1.32 to 5.13, $p = 0.006$) were also associated with dizziness. Carbamazepine was associated with memory impairment (AOR: 2.53, 95% CI 1.146 to 5.586, $p = 0.022$).

Discussion

This study found that epilepsy management continues to rely on older ASMs and the use of dual or polytherapy, a pattern that is closely linked to a considerable burden of treatment-related adverse events.

Carbamazepine, valproic acid, and clobazam were the drugs most frequently used in this study. A similar tendency of prescribing older ASMs was reported in India [20], Bangladesh [21], Indonesia [22], Colombia [23], and Ethiopia [24], where carbamazepine, phenytoin, valproic

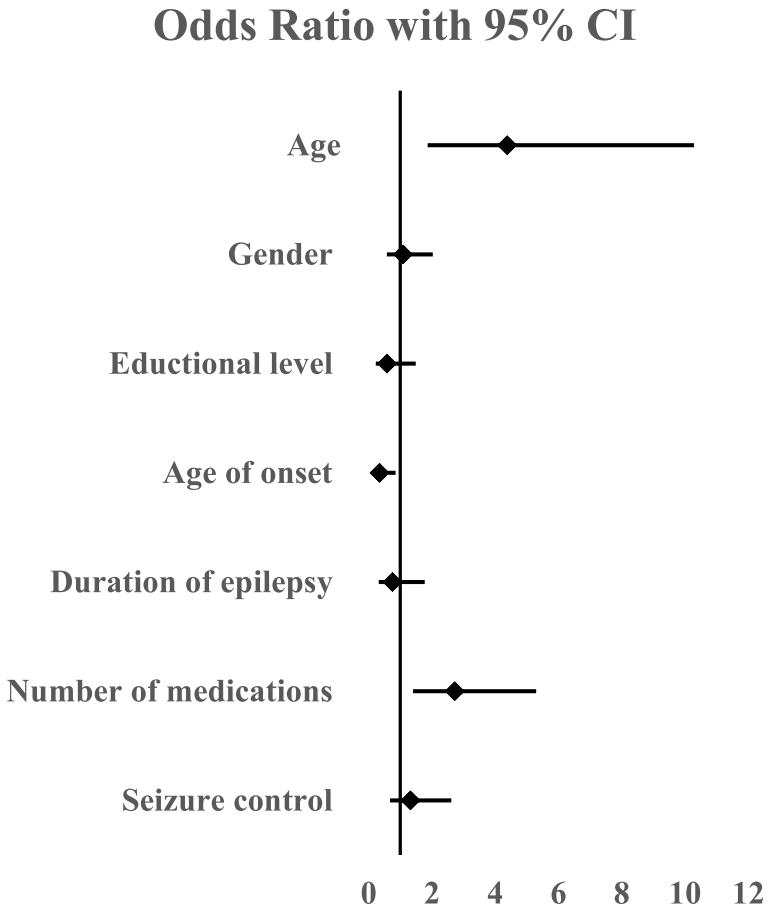

Fig. 2 Factors associated with adverse events of antiseizure medications. 95% CI, 95% confidence interval

Table 4 Antiseizure medications associated with the common adverse events

Antiseizure medication (n)	Sedation		Memory impairment		Dizziness	
	AOR	95% CI	AOR	95% CI	AOR	95% CI
Carbamazepine (120)	1.97	0.945 to 4.093	2.53	1.146 to 5.586	1.56	0.735 to 3.311
Valproic acid (81)	3.23	1.578 to 6.613	1.92	0.913 to 4.032	2.48	1.211 to 5.094
Clobazam (66)	2.82	1.438 to 5.541	1.75	0.869 to 3.525	2.60	1.321 to 5.133
Levetiracetam (63)	1.04	0.504 to 2.135	1.83	0.851 to 3.923	1.12	0.531 to 2.371
Clonazepam (25)	1.69	0.668 to 4.266	2.61	0.997 to 6.805	1.74	0.676 to 4.503
Topiramate (23)	1.18	0.433 to 3.198	2.15	0.739 to 6.250	1.30	0.489 to 3.463
Lamotrigine (19)	0.604	0.197 to 1.850	0.495	0.124 to 1.983	1.876	0.637 to 5.523
Phenytoin (14)	2.328	0.674 to 8.041	2.302	0.616 to 8.594	1.228	0.320 to 4.721

AOR Adjusted odds ratio, 95% CI 95% confidence interval

acid, and phenobarbital continue to be the main treatment options. These older ASMs remain widely used in many LMICs because they are effective, easier to obtain, and more affordable. In contrast, studies from high-income countries indicate a greater use of newer ASMs, which generally result in fewer adverse events and are more readily tolerated [14, 25]. The limited availability of these newer medications in LMICs may partly explain the higher rates of treatment-related adverse events seen in these settings.

The majority of the participants (64.8%) in this study were taking two or more ASMs. This was higher than what was reported in India [20] (46.6%), Colombia [23] (36%), Bangladesh [21] (33%), and Ethiopia [24] (17.8%). These same studies also documented lower frequencies of adverse events—49.2% in India, 42% in Colombia, 24.5% in Bangladesh, and 15% in Ethiopia. Since adverse events tend to occur more often when patients are treated with two or more medications rather than a single medication [26], the higher use of dual or polytherapy in our setting likely plays a role in the greater prevalence of adverse events seen in this study.

Focal seizures accounted for the majority of cases (60.6%), and most patients with focal epilepsy (68.2%) received dual or polytherapy. Focal seizures tend to be more medication-resistant than generalised seizures and generally require combination therapy for adequate control [27]. This provides further explanation for the higher prevalence of adverse events in the study.

Sedation, memory impairment and dizziness were commonly reported in this study. Valproic acid and clobazam were associated with sedation, and these same medications were also linked to a higher likelihood of dizziness. While carbamazepine was associated with memory impairment. These findings were consistent with the well-known central side-effect profiles of these medications [28]. Frequent use of these medications, particularly carbamazepine and valproic acid in this study, explains why these adverse events were commonly reported by participants. Similar patterns were found in studies from India [20], Colombia [23] and Ethiopia [24].

Furthermore, none of the newer agents showed significant association with the common adverse events in this study. This observation supports the claim that newer ASMs have better tolerability [12]. However, a smaller number of ASMs in this study could limit the power of detecting the effect.

Most patients who required switching of ASMs due to adverse events were intolerant to carbamazepine, and levetiracetam was used as the alternative in these patients [29].

Several factors, such as advancing age, early onset of epilepsy, the use of multiple ASMs, and having epilepsy for more than ten years, were associated with a higher likelihood of adverse events. Similar associations were reported in studies from India [30], Colombia [23], and Ethiopia [24], where both polytherapy and longer disease duration were linked to increased adverse events. These patterns are expected, as older individuals are more vulnerable to medication interactions, early onset of epilepsy leads to longer cumulative exposure to medications, and polytherapy is well recognised for increasing the burden of adverse events. Likewise, long-standing epilepsy and poor seizure control often prompt medication changes, such as dose escalation or the addition of other medications, all of which can increase the risk of treatment-related adverse events. In the present study, the occurrence of adverse events was almost equal in male and female participants. In contrast to our findings, a study conducted in Colombia reported a higher prevalence of adverse events among female patients receiving ASMs [23].

Though not significant, patients with lower educational levels and inadequate seizure control experienced more adverse events in the present study. Patient education and switching to better-tolerated ASMs would address these issues. However, physical and economic accessibility to newer ASMs may be challenging for resource-limited settings. Despite the proven safety and tolerability of newer ASMs, older ASMs are still predominantly used because of the affordability, particularly in LMIC [14–16]. A similar trend was observed in the present study,

and newer agents were mainly reserved for those who were intolerant to older ASMs or not controlled with single medication. Since the public health sector provides services free of charge in Sri Lanka, affordability limits the availability of medicines in the public sector [31]. As the Teaching Hospital, Jaffna, is a public sector hospital, this treatment pattern is understandable. Furthermore, the average ASM prescription per patient was almost 2, which was higher than reported in an Ethiopian study [24] (1.18). Dependence on older ASMs and use of multiple medications may play a major role in the high number of adverse events reported.

This study provides much-needed, locally relevant evidence on the prescribing patterns of antiseizure medications and the adverse events experienced by adults with epilepsy in a resource-limited setting, where such information is currently sparse. However, the study has several limitations. An important limitation is the frequency classification of adverse events used in this study, which can be influenced by sample size, and the small sample size precluded the ability to identify rare and many uncommon adverse events. Participants were recruited from a single tertiary-care hospital in Northern Sri Lanka, which may limit the generalisability of the findings to all people living with epilepsy in the country. In addition, adverse events were based on patient self-report, raising the possibility of recall or reporting bias.

Conclusion

This preliminary study in a single centre in Sri Lanka showed predominant use of older and multiple antiseizure medications despite the higher prevalence of adverse events associated with them. Advancing age, early onset of epilepsy, longer disease duration, polytherapy and poor seizure control increased the likelihood of experiencing adverse events. Further studies with larger and more diverse samples are needed to identify the factors that contribute to polytherapy, determine the safety and efficacy of current treatment practices, and explore the cost-effective treatment strategies to improve epilepsy care with a better quality of life.

Abbreviations

ASMs	Antiseizure medications
LMIC	Low- and middle-income countries
AORs	Adjusted odds ratios
CI	Confidence intervals
SD	Standard deviation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12883-026-04837-1.

Supplementary Material 1.

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Authors' contributions

YG, AK and TSN were involved in the research conception. The study was conceptualised by all three authors. YG was responsible for the data collection, and entry. All three involved in data analysis. First draft was written by YG and reviewed by TSN and AK. All authors read and approved the final manuscript.

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Data availability

Data are available on reasonable request. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the Ethics Review Committee, Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/24/155/NDR/0312). Informed written consent was obtained from all participants prior to enrolment in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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